



## Rapid and Efficient Development of Downstream Bio-Pharmaceutical Processing Alternatives

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# Rapid and Efficient Development of Downstream Bio-Pharmaceutical Processing Alternatives

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## Abstract

Downstream processing in pharmaceutical and bio-pharmaceutical production is becoming increasingly important due to the higher product yields desired as the minimum operating cost. As such, from a process development point of view, there is a need to rapidly and efficiently synthesize optimal downstream processing routes while taking into account a very narrow time line between approval of a product from a regulatory body (such as FDA) to the beginning of full scale production. This work in particular focusses on the design and synthesis for the recovery and purification of bio-pharmaceutical molecules produced through fermentation processes. To this end, this work adapts and extends the domain of application of the process synthesis methodology based on thermodynamic insights<sup>1</sup> for traditional chemical processes.

The first task in the methodology is to deal with a mixture analysis which allows to immediately screen out some separation techniques that are not suitable with the type of mixture considered. A binary ratio matrix is then computed to store the properties of the binary pairs of molecules: this method allows in determining the extent to which a separation technique is feasible for a binary separation task. As such this step allows the identification of all physically feasible separation techniques and the first separation tasks. Further screening on separation techniques can be done considering the conditions of operation (temperature and pressure) of single unit operations. This means that a particular separation technique, even if considered as physically feasible in previous steps, can be rejected whether extreme condition of temperature or pressure or both of them need to be achieved to carry out the operation. In the second and final step in the

methodology, further insight on the mixture properties are employed to find a set of physically feasible process pathways with an estimation of the conditions of operations for each flowsheet. The outcome of the work is thus to design a sequence of feasible processing routes. After the process synthesis, models of the different unit operations are used to simulate the process and to predict the behavior of the system. The methodology was then been applied for the synthesizing the downstream processing pathway of Lovastatin a molecule that is mainly exploited as an anti-hypercholesterolemia drug.

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(1) Jaksland, C. a.; Gani, R.; Lien, K. M. Separation Process Design and Synthesis Based on Thermodynamic Insights. *Chem. Eng. Sci.* **1995**, 50 (3), 511–530.

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